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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98N-0237]

**Agency Information Collection Activities; Announcement of OMB Approval; New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "New Drug and Biological Drug Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 5, 1999 (64 FR 53960), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0423. The approval expires on December 31, 2002. A copy of the supporting

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statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 10, 2000



**William K. Hubbard**

Senior Associate Commissioner for Policy, Planning,  
and Legislation

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